

REMARKS

I. STATUS OF CLAIMS

Claims 45-76 are pending. Claims 39-44 are cancelled without prejudice or disclaimer, and claims 45-76 are added herein. Written description support for the amendments can be found in the specification, e.g., page 4, lines 9-13 and 26-33, and the claims. Thus, no new matter is added by the amendments provided herein. Entry of the amendments is respectfully requested.

II. REJECTION UNDER 35 U.S.C. § 103

Claims 39-44 are rejected under 35 U.S.C. § 103(a) over BRYAN GRIFFITHS & DENIS LOOBY, *Scale-Up of Suspension and Anchorage-Dependent Animal Cells*, in 75 METHODS IN MOLECULAR BIOLOGY: BASIC CELL CULTURE PROTOCOLS 59, 59-75 (Jeffrey W. Pollard & John M. Walker eds., 2d ed. 1997) ("Griffiths") in view of "Friendship Cake/Bread History" available at <http://recipecircus.com> and "Amish Friendship Bread" available at <http://en.wikipedia.org>. Final Office Action dated May 7, 2008, at p. 4. In the Decision on Appeal mailed January 31, 2011 ("Decision"), the Board of Patent Appeals and Interferences ("Board") affirmed the Examiner's rejection. Decision at p. 6. Applicants hereby re-open prosecution of this application to present further amendments and arguments with regard to the § 103 rejection over Griffiths, "Friendship Cake/Bread History" and "Amish Friendship Bread," which was not previously considered by the Board.

Without acquiescing to the rejection, Applicant has cancelled claims 39-44 and added claims 45-76. New independent claim 45 recites that "the cells of the at least one first production batch in c) have a different passage number than the cells of the at

least one subsequent production batch in e). In addition, claim 45 recites that “the passage number of each production batch is between master cell bank and extended cell bank.” New independent claim 64 includes similar language. None of Griffiths, “Friendship Cake/Bread History,” or “Amish Friendship Bread” teach or suggest that a biological may be produced from production batches made according to the claimed invention in which those production batches have different passage numbers. On the contrary, conventional practice shows the production of biological occurs in production batches all having the same passage number. See, e.g., U.S. Patent No. 4,664,912 to Wiktor et al. (“Wiktor”) at col. 2, lines 68-69; see also Applicant’s specification at page 1, lines 15-20 and p. 4, lines 26-34. In addition, none of the cited references teach or suggest that the passage number of each production batch is between master cell and extended cell bank. Further, the validation and characterization of the extended cell bank, e.g., as in claims 63 and 76, guarantees that all passage numbers can safely be used for production without any further analytical efforts.

To establish a *prima facie* case of obviousness, the Examiner has the burden of establishing that the prior art references teach or suggest all the claim limitations. See *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (CCPA 1974). Because Griffiths, “Friendship Cake/Bread History,” and “Amish Friendship Bread” do not teach or suggest the “different passage number” aspect of Applicant’s claimed invention, a *prima facie* case of obviousness has not been made. Accordingly, Applicant respectfully requests that this obviousness rejection be withdrawn.

III. CONCLUSION

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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